



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,105	02/06/2002	Hideki Kambara	HITACHI.039A	4700
20995	7590	06/10/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			CELSA, BENNETT M	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,105

Applicant(s)

KAMBARA ET AL.

Examiner

Bennett Celsa

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/18/01.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Art Unit: 1639

DETAILED ACTION

Status of the Claims

Claims 1-28 are currently pending.

Claims 1-14 and 24-28 are withdrawn from consideration.

Claims 15-23 are under consideration.

Election/Restrictions

Applicant's election of Group I (claims 15-23 drawn to a probe array) in the reply filed on 5/3/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's request for rejoinder of claims 1-14 upon allowance of claim 15 is noted.

Applicant's further election of "polynucleotide" as the probe species and "capillary" as the array species in the reply filed on 5/3/04 which reads on claims 15-23 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1639

Claims 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 15 (and claims dependent thereon), the phrase "aligned in a designated order" is indefinite as to what "alignment" (e.g. configuration) corresponds or does not correspond to the claimed invention.

B. In claim 18, the term "fine particles" is a relative term which renders the claim indefinite. The term "fine particles" is not defined by the claim, nor does the specification provide a standard for ascertaining the requisite "fineness" degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, what (e.g. compositions, size, shape etc.) distinguishes a bead from a fine particle? Is a "bead" or "microbead" a "fine particle"?

C. In claim 20, the term "solid pieces as markers" is indefinite as to what is being marked (e.g. indicated) by the utilization of "solid piece markers". Does this refer merely to position of probe attachment or does it refer in some manner to sample solution analysis (e.g. hybridization of probes with analyte)?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1639

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-21 and 23 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Muller et al. US Pat. No. 5,804,384 (9/98: filed 12/96).

The presently claimed invention is directed to:

A probe array "for analyzing a sample solution passing therethrough"

comprising:

- i. plural types of "probes" immobilized on surfaces of different "solid pieces"; and
- ii. an array wherein the probe-immobilized solid pieces are aligned in a

"designated order".

- "probes" include polynucleotides, peptides or proteins (polynucleotides as elected species);

- "array" can be a capillary, groove or optical cell (capillary as elected species).

- "solid pieces" include "beads" and "fine particles".

It is noted that intended use language e.g. the use of the array "for analyzing a sample solution passing therethrough" and intended use of nucleotides, peptides or proteins as "probes" is not afforded patentable weight in a composition claim.

Muller et al. teach (e.g. see abstract; figure 1; col. 7-8; patent claims) a "tube" (e.g. a capillary tube as in present claim 23) containing a "linear" (one dimensional as in

Art Unit: 1639

present claim 19) array of specific binding elements that each have capture probes specific for a target analyte linked thereto wherein: the reference "binding elements" correspond to "solid pieces" which are "beads" (e.g. present claim 17) or "fine particles" (e.g. microbeads as in present claim 18) as presently claimed and the reference's immobilized "capture probes" (e.g. probes as presently claimed) can be nucleotides or proteins (e.g. peptides). The "binding elements" can be stacked directly on top of each other (e.g. one-dimensional arrangements: and "aligned in a designated order") (see reference col. 7) wherein the binding elements can be distinguished from each other from the use of "inert spacers" (e.g. without capture probes) which correspond to solid piece markers as presently claimed (e.g. present claim 20: see reference column 8). The Muller reference teaches the same intended use of its "array" as presently claimed e.g. "for analyzing a sample solution passing therethrough".

Claims 15-19 and 21 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Christel et al. WO 99/09042 (2/99: filed 7/98 or earlier).

The presently claimed invention is directed to:

A probe array "for analyzing a sample solution passing therethrough" comprising:

- i. plural types of "probes" immobilized on surfaces of different "solid pieces"; and
- ii. an array wherein the probe-immobilized solid pieces are aligned in a "designated order".

Art Unit: 1639

- "probes" include polynucleotides, peptides or proteins (polynucleotides as elected species);
- "array" can be a capillary, groove or optical cell (capillary as elected species).
- "solid pieces" include "beads" and "fine particles".

It is noted that intended use language e.g. the use of the array "for analyzing a sample solution passing therethrough" and intended use of nucleotides, peptides or proteins as "probes" is not afforded patentable weight in a composition claim.

Christel et al. teach a microfluidic device (e.g. see abstract; figures, especially figures 13 and 14) composed of an internal chamber comprising an internal surface which preferably comprises an array of columns for capturing the desired material which is flowed through the chamber. Accordingly, the reference teaches the presently claimed intended array use e.g. "for analyzing a sample solution passing therethrough". The reference "internal attachment surfaces" are formed by one or more solid surfaces (e.g. "solid pieces" as presently claimed) which include "beads" (e.g. as in present claim 17) or "fibers" (e.g. "particles" as in present claim 18) which individually capture and "immobilize" "nucleic acid" (e.g. probes as presently claimed) forming a two dimensional array (e.g. X/Y axis as in figure 14) or one dimensional array (e.g. columns formed within chamber 26). See figure 14 and pages 45-46.

Claims 15-23 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kambara et al. US. Pat. No. 6,288,220 (9/01: filed 3/99).

The presently claimed invention is directed to:

Art Unit: 1639

A probe array "for analyzing a sample solution passing therethrough" comprising:

- i. plural types of "probes" immobilized on surfaces of different "solid pieces"; and
- ii. an array wherein the probe-immobilized solid pieces are aligned in a

"designated order".

- "probes" include polynucleotides, peptides or proteins (polynucleotides as elected species);

- "array" can be a capillary, groove or optical cell (capillary as elected species).

- "solid pieces" include "beads" and "fine particles".

It is noted that intended use language e.g. the use of the array "for analyzing a sample solution passing therethrough" and intended use of nucleotides, peptides or proteins as "probes" is not afforded patentable weight in a composition claim.

Kambara et al. disclose and claim a probe array for analyzing a sample solution comprising a plurality of probes (e.g. DNA, peptide/protein) immobilized on solid surfaces (e.g. beads/ (fine) particles) in both a one or two dimensional arrangement which are "aligned in a designated order" in which the array includes a capillary or a groove with the use of "marker" beads/particles of different sizes. See e.g. Abstract; figures; col. 2-6; patent claims 1-14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1639

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. US Pat. No. 5,804,384 (9/98: filed 12/96) and Yguerabide et al. US Pat. No. 6,214,560 (4/01: filed 4/97 or earlier).

The presently claimed invention is directed to:

A probe array "for analyzing a sample solution passing therethrough"
comprising:

Art Unit: 1639

i. plural types of “probes” immobilized on surfaces of different “solid pieces”; and
ii. an array wherein the probe-immobilized solid pieces are aligned in a
“designated order”.

- “probes” include polynucleotides, peptides or proteins (polynucleotides as
elected species);

- “array” can be a capillary, groove or optical cell (capillary as elected species).

- “solid pieces” include “beads” and “fine particles”.

It is noted that intended use language e.g. the use of the array “for analyzing a
sample solution passing therethrough” and intended use of nucleotides, peptides or
proteins as “probes” is not afforded patentable weight in a composition claim.

Muller et al. teach (e.g. see abstract; figure 1; col. 7-8; patent claims) a “tube”
(e.g. a capillary tube as in present claim 23) containing a “linear (one dimensional as in
present claim 19) array of specific binding elements that each have capture probes
specific for a target analyte linked thereto wherein: the reference “binding elements”
correspond to “solid pieces” which are “beads” (e.g. present claim 17) or “fine particles”
(e.g. microbeads as in present claim 18) as presently claimed in which the reference
immobilized “capture probes” (e.g. probes as presently claimed) can be nucleotides or
proteins (e.g. peptides). The “binding elements” can be stacked directly on top of each
other (e.g. one-dimensional arrangements: and “aligned in a designated order”) (see
reference col. 7) wherein the binding elements can be distinguished from each other
from the use of “inert spacers” (e.g. without capture probes) which correspond to solid
piece markers as presently claimed (e.g. present claim 20: see reference column 8).

Art Unit: 1639

The Muller reference teaches the same intended use of its "array" as presently claimed e.g. "for analyzing a sample solution passing therethrough".

The Muller reference array differs from the presently claimed invention (e.g. claim 22) by failing to teach the use of *different sized* solid pieces (beads/particles) as "markers" in the Muller arrays.

Yguerabide et al. teach a method for the detection and measurement of one or more analytes in a sample (including the use of a DNA array e.g. see examples, especially examples 30-34, most especially example 32; and patent claims) which is extremely sensitive (e.g. more sensitive than the use of fluorophores) resulting from its utilization of different beads/particle size/shape and/or composition (e.g. discrete individual "markers") in various combinations in its arrays in order to generate more easily detectable and measurable light scattering signals. See e.g. abstract; col. 9-12.

Accordingly, the Yguerabide et al. reference would provide motivation to one of ordinary skill in the art to modify the Muller reference array in order to incorporate the use of different size/shaped beads/particles in order to obtain a more sensitive assay for the detection and measurement of one or more analytes in a sample.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Muller reference array to incorporate different sized particle/beads to serve as "markers" in order to obtain a more sensitive assay by measurement of light scattering signals for better detection of one more analytes in a sample in accordance with the Yguerabide et al. teaching.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No.6, 288,220. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims a probe array for analyzing a sample solution comprising a plurality of probes (e.g. DNA, peptide/protein) immobilized on solid surfaces (e.g. beads/ (fine) particles) in both a one or two dimensional arrangement and a "aligned in a designated order" in which the array includes a capillary or a groove with the use of "marker" beads/particles of different sizes which is a "species" of probe array within the scope of the presently claimed invention.

Art Unit: 1639

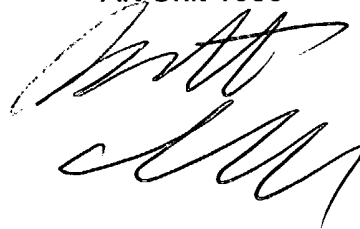
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639



BC
June 7, 2004